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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,873	09/05/2003	Shyam S. Mohapatra	USF-182XC1	6872

23557 7590 07/06/2007

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EXAMINER	
NOBLE, MARCIA STEPHENS	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
07/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	10/655,873	MOHAPATRA ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Marcia S. Noble*.

(2) *Peter Paras*.

(3) *Glen Ladwig*.

(4) *Jay Pattumtti*.

Date of Interview: *12 June 2007*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: _____.

Identification of prior art discussed: _____.

Agreement with respect to the claims f)☐ was reached. g)☐ was not reached. h)☒ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

PETER PARAS, JR.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant's Representative, Glen Ladwig, requested an interview to discuss the outstanding non-final office action and to determine if the draft provided to the examiners by fascimile (see attachment) would address the issues of the outstanding office action. The new matter rejection was discussed in light of the proposed amendments. Applicant was informed that the amendments to the claims would address the new matter rejection of record. With regards to the 112, 2nd paragraph issues, Applicant was informed that the amendments only addressed some of the issues in the rejection. It was pointed out that proposed claims 7 and 8 disclose amino acid sequences comprising SEQ ID NOS that are nucleic acids and therefore it is still not clear if the claims are to the nucleic acid or protein. Applicant was advised to check that all the claims to SEQ ID NOS accurately correspond to the type of molecule being claimed. In regard to the 103(a) rejection, Applicant was reminded that this rejection is now only encompassing the product claims and not the method claims. Applicant asserted that the art of record teaches away from the combination of the vectors as claimed and therefore would not be obvious. Examiners explained that the two vectors were established in the art for use in inducing an immunological response and therefore would be obvious. It was suggested to Applicant that they file their response and that the examiners will consider it very closely. In regards to the enablement rejection, Applicant was informed that the amendment addressed some of the enablement issues of record but not all. More specifically, the instant claims still do not address the issues of unpredicatbility of route of administration. It was suggested either the claims be amended to include an enabled route of administration or Applicant provide evidence that the art enables various routes of administration in this specific invention. Applicant was also informed that the breadth of claiming an increase in Th1-type cytokines and a decrease in Th2-type cytokines is still not enabled. Applicant was also informed that some of the claims were amended to recite 'an increase of IgG2a specific to the antigen', which would address the enablement issue of any IgG2a not being enabled. However, not all the independent claims have this amendment and still encompass any IgG2a. Therefore some of the claims still encompass this enablement issue. Applicant had also been informed that restructuring the language for the agents that are to be co-administered in the independent claims is advisable because as written the agents to be coadministered are not easily discerned by the claim language .

FACSIMILE COVER SHEET

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TO: Examiner Marcia Stephens Noble
Spr. Examiner Peter Paras
Examining Group 1632

FROM: Glenn P. Ladwig
Patent Attorney
Registration No. 46,853

COMPANY: United States Patent and Trademark Office

DATE: June 11, 2007

FAX NO.: (571)273-5545
(571)273-4517

NO. OF PAGES (INCLUDING COVER SHEET): 13

SUBJECT/MESSAGE:

INFORMAL COMMUNICATION—DO NOT ENTER

Re: U.S. Patent Application Docket No. USF-182XC1
GENETIC ADJUVANTS FOR IMMUNOTHERAPY
Serial No.: **10/655,873**; Date filed: September 5, 2003
Applicants: Mohapatra, Kumar

Dear Examiners Noble and Paras:

Attached for your review is an agenda for our telephonic interview on Tuesday, June 12, 2007 at 2:00 p.m.

Sincerely,

Glenn P. Ladwig

If you do not receive all pages or if any transmission is not legible, call the sender at (352) 375-8100.

J:\USF\182XC1\PTO\FAX-AGENDA.DOC/DNB/mv

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Marcia Stephens Noble
Art Unit	:	1632
Applicants	:	Shyam S. Mohapatra, Mukesh Kumar
Serial No.	:	10/655,873
Filed	:	September 5, 2003
Confirm. No.	:	6872
For	:	Genetic Adjuvants for Immunotherapy

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMAL COMMUNICATION—DO NOT ENTER

USF-182XC1---Telephonic Interview Agenda for 2:00 p.m., June 12, 2007

Following are proposed claim amendments and a summary of the rejection set forth in the Office Action dated February 26, 2007, with the applicants' comments.

I. Proposed Claims:

Claim 1 (Currently amended): ~~A method for modulating an immune response, comprising~~ administering to a patient an ~~effective amount of a nucleic acid sequence encoding IL-12,~~ and an operably linked promoter sequence~~; and an effective amount of a nucleic acid sequence encoding IFN-γ, and an operably linked promoter sequence, such that the administering results in an increase of Th1-type cytokine production, an increase of IgG2a levels, a decrease of Th2-type~~ cytokine production~~, and reduced serum IgE levels.~~ A method for modulating an immune response, comprising co-administering to a patient an effective amount of a nucleic acid sequence encoding p35 and p40 subunits of human IL-12, and a promoter sequence operably linked to the nucleic acid sequence encoding the p35 and p40 subunits;

an effective amount of a nucleic acid sequence encoding human IFN-γ, and a promoter sequence operably linked to the nucleic acid sequence encoding human IFN-γ, and

an antigen, such that the co-administering results in an increase of Th1-type cytokine production, an increase of IgG2a specific to the antigen, a decrease of Th2-type cytokine production, and reduced serum IgE levels.

Claim 2 (Cancel)

Claim 3 (Currently amended): ~~The method of claim 1, wherein the administering step includes selecting the IL-12 to comprise a p35 subunit and a p40 subunit, the p35 subunit to comprise an amino acid sequence of SEQ ID NO:8, and the p40 subunit to comprise an amino acid sequence of SEQ ID NO:10~~ The method of claim 1, wherein the step of co-administering the nucleic acid sequence encoding the p35 and the p40 subunits of human IL-12 results in expression of the p35 and the p40 subunits, the p35 subunit comprising an amino acid sequence of SEQ ID NO:8, and the p40 subunit comprising an amino acid sequence of SEQ ID NO:10.

Claim 4 (Cancel)

Claim 5 (Cancelled)

Claim 6 (Currently amended): The method of claim 1, wherein ~~the administering step~~ includes selecting the step of co-administering the nucleic acid sequence encoding the human IFN-γ results in expression of the human IFN-γ comprising ~~to comprise~~ an amino acid sequence of SEQ ID NO:12.

Claim 7 (Currently amended): The method of claim 1, wherein ~~the administering step~~ includes selecting the step of co-administering the nucleic acid sequence encoding the p35 and the p40 subunits of the human IL-12 results in expression of the subunits comprising ~~to comprise~~ SEQ ID NO:7 and SEQ ID NO:9.

Claim 8 (Currently amended): The method of claim 1, wherein ~~the administering step includes selecting the~~ step of co-administering the nucleic acid sequence encoding the human IFN-γ ~~to comprise~~ results in expression of the human IFN-γ comprising SEQ ID NO:11.

Claim 9 (Previously presented): The method of claim 1, wherein the nucleic acid sequences are administered with a pharmaceutically acceptable carrier.

Claim 10 (Cancelled)

Claim 11 (Previously presented): The method of claim 1, wherein the nucleic acid sequences are administered within separate DNA plasmids.

Claim 12 (Previously presented): The method of claim 1, wherein the nucleic acid sequences and promoter sequences are administered within a viral vector.

Claim 13 (Cancelled)

Claim 14 (Cancel)

Claim 15 (Currently amended): The method of ~~claim 14~~ claim 1, wherein the antigen is selected from the group consisting of a protein, peptide, glycoprotein, carbohydrate, lipid, glycolipid, hapten conjugate, recombinant nucleotides, killed or attenuated organism, toxin, toxoid, and organic molecule.

Claims 16-17 (Cancelled)

Claim 18 (Currently amended): The method of ~~claim 14~~ claim 1, wherein the antigen is administered to the patient with the nucleic acid sequences and a pharmaceutically acceptable carrier.

Claim 19 (Original): The method of claim 1, wherein the patient is human.

Claims 20-21 (Cancel)

Claim 22 (Cancelled)

Claims 23-31 (Cancel)

Claims 32-42 (Cancelled)

Claim 43 (Currently amended): ~~A method for modulating an immune response, comprising administering to a patient an effective amount of a plasmid comprising a nucleic acid sequence encoding IL-12, and an operably linked promoter sequence; and an effective amount of a plasmid comprising a nucleic acid sequence encoding IFN-γ, and an operably linked promoter sequence, such that the administering results in an increase of Th1 type cytokine production, an increase of IgG2a levels, a decrease of Th2 type cytokine production, and reduced serum IgE levels~~ A method for modulating an immune response, comprising co-administering to a patient an effective amount of a plasmid comprising a nucleic acid sequence encoding p35 and p40 subunits of human IL-12, and a promoter sequence operably linked to the nucleic acid sequence encoding the 35 and p40 subunits; and

an effective amount of a plasmid comprising a nucleic acid sequence encoding human IFN-γ,

and a promoter sequence operably linked to the nucleic acid sequence encoding the human IFN-γ,

and an antigen; such that the co-administering results in an increase of Th1-type cytokine production, an increase of IgG2a levels, a decrease of Th2-type cytokine production, and reduced serum IgE levels.

Claim 44 (Cancel)

Claim 45 (Currently amended): The method of ~~claim 44~~ claim 43, wherein the administering step includes ~~selecting the antigen to comprise an allergen~~ the antigen comprises an allergen.

Claim 46 (Currently amended): The method of ~~claim 44~~ claim 43, wherein the administering step includes ~~selecting to comprise Kentucky blue grass (KBG) allergen extract~~ the antigen comprises Kentucky blue grass (KBG) allergen extract.

Claim 47 (Currently amended): The method of claim 43, wherein the administering step includes selecting the operably linked promoters to comprise ~~cytomegalovirus (CMV)~~ promoters the operably linked promoters comprise cytomegalovirus (CMV) promoters.

Claim 48 (Currently amended): The method of ~~claim 44~~ claim 43, wherein the administering step includes ~~selecting the antigen to comprise Kentucky blue grass (KBG) allergen extract, and the operably linked promoters to comprise cytomegalovirus (CMV)~~ promoters the antigen comprises Kentucky blur grass (KBG) allergen extract, and wherein the operably linked promoters comprise cytomegalovirus (CMV) promoters.

Claim 49 (Previously presented): The method of claim 43, wherein the patient is human.

Claim 50 (Currently amended): ~~The method of claim 43, wherein the administering step includes selecting the IL-12 to comprise amino acid sequences of SEQ ID NO:8 and SEQ ID NO:10, and the IFN-γ to comprise an amino acid sequence of SEQ ID NO:12~~ The method of

claim 43, wherein the step of co-administering the nucleic acid sequence encoding IL-12 results in expression of the p35 and the p40 subunits comprising amino acid sequences of SEQ ID NO:8 and SEQ ID NO:10, and the nucleic acid sequence encoding human IFN-γ results in expression of the human IFN- γ having an amino acid sequence of SEQ ID NO:12.

Claim 51 (Cancelled)

Claim 52 (Previously presented): The method of claim 43, wherein the patient suffers from a condition selected from the group consisting of allergy, allergic rhinitis, atopic dermatitis, asthma, allergic sinusitis, pulmonary fibrosis, and cancer.

Claim 53 (Previously presented): The method of claim 43, further comprising administering an antigen to the patient, wherein the plasmids are administered by a route selected from the group consisting of intramuscularly, orally, and intranasally.

Claim 54 (Currently amended): ~~A pharmaceutical composition comprising a plasmid comprising a nucleic acid sequence encoding IL-12, and an operably linked promoter; a plasmid comprising a nucleic acid sequence encoding IFN-γ and an operably linked promoter; and a pharmaceutically acceptable carrier~~ A pharmaceutical composition comprising a plasmid comprising a nucleic acid sequence encoding p35 and p40 subunits of human IL-12, and a promoter operably linked to the nucleic acid sequence encoding the p35 and p40 subunits;

a plasmid comprising a nucleic acid sequence encoding human IFN-γ and a promoter operably linked to the nucleic acid sequence encoding the human IFN-γ;

and a pharmaceutically acceptable carrier.

Claim 55 (Previously presented): The pharmaceutical composition of claim 54, wherein said composition further comprises an antigen.

Claim 56 (Previously presented): The pharmaceutical composition of claim 55, wherein said antigen is an allergen.

Claim 57 (Currently amended): ~~The pharmaceutical composition of claim 54, wherein said IL-12 comprises the amino acid sequences of SEQ ID NO: 8 and SEQ ID NO:10, and wherein said IFN-γ comprises the amino acid sequence of SEQ ID NO:12~~ The pharmaceutical composition of claim 54, wherein the nucleotide sequences encoding the p35 and p40 subunits of the human IL-12 results in expression of the subunits having the amino acid sequences of SEQ ID NO: 8 and SEQ ID NO:10, and wherein the nucleotide sequence encoding the human IFN-γ results in expression of the human IFN-γ having an amino acid sequence of SEQ ID NO:12.

Claim 58 (Currently amended): The method of claim 1, wherein the nucleic acid sequence encoding the p35 and p40 subunits of the human IL-12 and the nucleic acid sequence encoding the human IFN-γ are administered to the patient through a mucosal route.

Claim 59 (Cancel)

Claim 60 (Currently amended): The method of claim 1, wherein the nucleic acid sequence encoding the p35 and p40 subunits of the human IL-12 and the nucleic acid sequence encoding the human IFN-γ are administered to the patient intranasally.

Claim 61 (Cancel)

Claim 62 (Previously presented): The method of claim 43, wherein the plasmids are administered to the patient through a mucosal route.

Claim 63 (Cancel)

Claim 64 (Previously presented): The method of claim 43, wherein the plasmids are administered to the patient intranasally.

Claim 65 (Cancel)

Claim 66 (Previously presented): The method of claim 1, wherein the patient suffers from a condition selected from the group consisting of allergy, allergic rhinitis, atopic dermatitis, asthma, allergic sinusitis, pulmonary fibrosis, and cancer.

Claim 67 (Cancel)

Claim 68 (Previously presented): The pharmaceutical composition of claim 54, wherein said composition increases Th1-type cytokine production, increases IgG2a, decreases Th2-type cytokine production, and reduces serum IgE *in vivo*.

II. Claims 20, 21, 23-31, 54-58, 67, and 68 have been rejected under 35 U.S.C. §103(a) as being obvious over Hogan *et al.* (*Eur. J. Immunol.*, 1998, 28:413-423), in view of Li *et al.* (*J. Immunol.*, 1996, 157:3216-3219), Dow *et al.* (U.S. Patent No. 6,693,086), and O'Donnell *et al.* (*J. Immunol.*, 1999, 163:4246-4252).

When the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be non-obvious. *KSR International Co. v. Teleflex Inc.*, 550 U.S. __ 2007, citing *United States v. Adams*, 383 U.S. 39, 51-52 (1966). The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results. *Id.* In this case, the references would not be combined by a person of ordinary skill in the art, where the references teach away from each other.

For example, Hogan, (see pg, 418-419, last paragraph to beginning of page 419) states, "although the protective effects of IL-12 were apparently mediated via the activity of

endogenous IFN-gamma, in our study, the use of the former may nevertheless represent a superior approach to vector-directed gene therapy of allergy. We have found that gene transfer of IFN-gamma was far less protective against disease in this model (unpublished data) possibly because of the short half-life of the factor...." Hence, a person of ordinary skill in the art would not combine Hogan with any of the cited references where the references teach away from each other. In addition, the applicant reiterates the same arguments previously made with reference to Hogan.

Furthermore, Dow teaches away from the composition of the claims, as are amended. Dow states that "traditional naked DNA delivery, which has been touted as having an adjuvant effect, is far less effective than the present compositions at stimulating a non-antigen specific immune response. (See Col. 12, lns. 13-17). By contrast, the background of the application notes that the "direct effects of these cytokine plasmids as genetic adjuvants in the allergen vaccines used for AIT have not been addressed." (page 2, lns. 12-13.) Furthermore, like the Li reference, Dow employs cationic liposomes, and teaches away from using viral vectors used by Hogan by noting that "unlike many protocols for administration of viral vector-based genetic vaccines, the present method can be used to repeatedly deliver the therapeutic composition described herein without consequences associated with some non-specific arms of the immune response, such as the complement cascade. (Col. 12, lns. 18-22.)

In addition, the O'Donnell publication merely observes that intravesical co-administration of BCG plus rIL-12 augments urinary IFN-γ production more strongly that either single agent alone, providing an immunological basis for using exogenous IL-12 in conjunction with BCG for bladder cancer immunotherapy. This observed increase in IFN-γ production upon co-administration of IL-12 and antigen does not provide a reasonable expectation of success in increasing Th1-type cytokine production and decreasing Th2-type cytokine production by administering a plasmid encoding nucleic acid sequences encoding human IL-12 and human IFN-γ.

With regard to claim 68, the combination of references would not necessarily produce the same predictable results. For example, the Hogan reference, (see page 415, last paragraph, to page 416, first line), notes that treated mice had IgG2a antibody levels that were similar to those

found in controls. This is different from the composition claimed in claim 68, wherein one of the effects is to increase IgG2a. Thus, claims 54-58, and 68 are non-obvious over the cited references.

III. Claims 2-4, 6-8, 45-48, and 50 have been rejected under 35 U.S.C. §112, first paragraph, as claiming new matter.

Claims 2-4, 6-8, 45-48, and 50 have been rejected under 35 U.S.C. §112, first paragraph, as claiming new matter. Claims 2 and 4 have been cancelled. Claims 3,6, 7, 8, 45-48, and 50 have been amended. No new matter has been entered.

IV. Claims 1-4, 6-9, 11, 12, 14, 15, 18-21, 23-31, 43-50, and 52-68 have been rejected under 35 U.S.C. §112, first paragraph, as non-enabled by the subject specification.

Claims 1-4, 6-9, 11, 12, 14, 15, 18-21, 23-31, 43-50, and 52-68 have been rejected under 35 U.S.C. §112, first paragraph, as non-enabled by the subject specification.

Claims 1 and 43 have been amended to recite "....nucleic acid sequence encoding p35 and p40 subunits of human IL-12.. ." Thus, the claims as amended, encompass an expression vector that is operable and encodes the p35 and p40 subunits of human IL-12. In addition, the claims, as amended, encompass a promoter that is operably linked to the gene of interest. Moreover, the claims, as amended, encompass encoding amino acid sequences that have the biological activity of IL-12 and IFN-γ and thus, results in the Ig and cytokine expression profile claimed.

As the court in *Liebel* recently stated, a "specification need not necessarily describe how to make and use every embodiment of the invention, because the artisan's knowledge of the prior art and routine experimentation can often fill in gaps." *Liebel-Flarsheim Co. v. Medrad*, WL 851205 at *8 (Fed. Cir. 2007), citing *AK Steel Corp. v. Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). Nevertheless, numerous preferred examples of administration are taught in the specification and administration is not necessarily unpredictable.

In addition to intramuscular administration and subcutaneous injection, the applicant teaches other forms of administration. For example, the third paragraph of page 12 of the

specification incorporates U.S. Patent No. 6,489,306 by reference. The '306 patent describes an example of intranasal administration that may be used to administer the nucleotide sequences claimed in this application. Thus, the applicant need not describe every administration route.

With regard to the cited references, Van Drunen Little van den, notes that cytokine co-administration might enhance the efficacy of DNA vaccines. (See page 119, second paragraph.) Scheerlick also notes that it is clear that cytokines... can be used to modulate DNA vaccines. (See page 2653, concluding remarks, first three lines.) Although the examiner cites Gautam for the proposition that various barriers to delivery exist, nothing in the Gautam reference mentions the use of cytokines for promoting enhanced delivery, where the naked DNA itself includes cytokine nucleotide sequences.

Yang is focused on gene therapy in the cardiovascular system, and is inapplicable to this application. Hence, the cited discussion about passive diffusion catheters does not apply. Moreover, Yang notes that most investigations about the imaging of gene therapy involve non-cardiovascular systems, which include the subject matter of the current application. (See page 36, fifth paragraph.)

With regard to the method of delivery, the claims have been amended to recite, "co-administering." Thus, the method of delivering the two cytokines are enabled.

The expression profile of the cytokines in the specification represents the full breadth of Th1 type cytokine production and Th2 type cytokine production. For example, the application on page 31, first paragraph, notes that IL-12 is the primary determinant of Th1 differentiation endogenously synthesized IFN-γ, both accelerates and enhances the Th1 differentiating effects of IL-12. Hence, the expression profiles of the representative Th1 and Th2 cytokines are predictive of the class of the Th1 and Th2 cytokines, as shown by the examples provided.

V. Claims 1-4, 6-9, 11, 12, 14, 15, 18-21, 23-31, 43-50, and 52-68 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite.

Claims 1-4, 6-9, 11, 12, 14, 15, 18-21, 23-31, 43-50, and 52-68 have been rejected under 35 U.S.C. §112, second paragraph, as indefinite.

By this Amendment, independent claims 1, 43, and 54 have been amended to make clear that the promoter sequences are operably linked to the nucleic acid sequences encoding the p35 and p40 subunits of human IL-12 and human IFN-γ. Thus, the claims are not indefinite.

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record
A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews
Paragraph (b)
In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.
All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:
- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:
1) A brief description of the nature of any exhibit shown or any demonstration conducted,
2) an identification of the claims discussed,
3) an identification of the specific prior art discussed,
4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
5) a brief identification of the general thrust of the principal arguments presented to the examiner,
   (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
6) a general indication of any other pertinent matters discussed, and
7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.